

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2012-0740; FRL-9366-7]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 20 chemical substances which were the subject of premanufacture notices (PMNs). Eight of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 20 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on [insert date 60 days after date of publication in the **Federal Register**]. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on [insert date 14 days after date of publication in the **Federal Register**].

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before [insert date 30 days after date of publication in the Federal Register] (see Unit VI. of the SUPPLEMENTARY INFORMATION).

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2012-0740, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments.
- Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2012-0740. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2012-0740. EPA's policy is that all comments received will be included in the docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact

information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at http://www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at http://www.regulations.gov, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject

to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at

19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see §721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

- B. What Should I Consider as I Prepare My Comments for EPA?
- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
 - 2. Tips for preparing your comments. When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
 - vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue

of April 24, 1990 (55 FR 17376) (April 24, 1990 SNUR). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in §721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to §721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6,

or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 20 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 20 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for nonconfidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
 - Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
 - CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes 8 PMN substances that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "5(e) SNURs" on these

PMN substances are promulgated pursuant to §721.160, and are based on and consistent with the provisions in the underlying consent orders. The 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) consent order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that airborne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) consent orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the §721.63 respirator requirements may request to do so under §721.30. EPA expects that persons whose §721.30 requests to use the NCELs approach for SNURs are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This rule also includes SNURs on 12 PMN substances that are not subject to

consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use." These so-called "non-section 5(e) SNURs" are promulgated pursuant to \$721.170. EPA has determined that every activity designated as a "significant new use" in all non-section 5(e) SNURs issued under \$721.170 satisfies the two requirements stipulated in \$721.170(c)(2), i.e., these significant new use activities, "(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified" for the PMN substance.

PMN Number P-11-135

Chemical name: Benzoic acid, 4-[(1-oxodecyl)oxy]-.

CAS number: 86960-46-5.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a cleaning enhancer additive for laundry and automatic dish-washing products.

Based on test data on the PMN substance, and ecological structural activity relationship (EcoSAR) analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 18 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range

from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 18 ppb for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any domestic manufacture or use of the substance other than as described in the PMN could result in exposures which may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at §721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (Office of Pollution Prevention and Toxic Substances (OPPTS) Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance. Due to low water solubility, EPA also recommends that the special considerations for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media.

CFR citation: 40 CFR 721.10611.

Chemical names: Distillates (lignocellulosic), C5-40 (P11-327); Paraffin waxes (lignocellulosic) hydrotreated, C5-40- branched, cyclic and linear (P-11-328); Naphtha

PMN Numbers P-11-327, P-11-328, P-11-329, P-11-330, P-11-331, and P-11-332

(lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear (P-11-330); Distillates

(lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (P-11-329); Kerosene

(lignocellulosic), hydrotreated, C8-26 - branched, cyclic, and linear (P-11-331); and

Residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear (P-11-332).

CAS numbers: 1267611-99-3 (P-11-327), 1267611-06-2 (P-11-328), 1267611-35-7 (P-11-329), 1267611-14-2 (P-11-330), 1267611-11-9 (P-11-331), and 1267611-71-1 (P-11-332).

Effective date of TSCA section 5(e) consent order: July 21, 2012.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (nonconfidential) uses of the PMN substances will be as a distillation feedstock after hydrotreatment (P-11-327), as a feedstock (P-11-328), as a blend-stock for conventional fossil fuels (P-11-329, P-11-330, and P-11-331) and use in a manner comparable to gas oil as it is currently used in industry (P-11-332). These PMNs are complex mixtures and have been assessed based on the toxic components within their mixture. The most important and primary component present is benzene. Based on this analysis, EPA identified concerns for oncogenicity, immunosuppression, and skin sensitization (defatting of the skin tissue) to workers exposed to the PMN substances. The EPA Maximum Contaminant Level for benzene in drinking water is 5 ppb. The PMNs' new chemical exposure limit (NCEL) is 0.32 milligram/cubic meter (mg/m³) as an 8-hour time-weighted average. In addition, based on EcoSAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 82 ppb for P-11-329 and P-11-331, and 180 ppb for P-11-327, P-11-328, P-11-330, and P-11-332. However, EPA does not expect risk to aquatic organisms at the expected levels and duration of exposure as described in the PMNs. The consent order was issued under TSCA sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) based on a finding

that these substances may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the consent order requires:

- 1. Use of personal protective equipment including dermal protection when there is potential dermal exposure and a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 10,000, or compliance with a NCEL of 0.32 mg/m3 as an 8-hour time-weighted average when there is potential inhalation exposure.
- 2. No use of the substances resulting in surface water concentrations exceeding 5 ppb of the combination of these PMN substances.
 - 3. Establishment and use of a hazard communication program.

The SNUR designates as a "significant new use" the absence of these protective measures.

Recommended testing: EPA has determined that a combined chronic toxicity/carcinogenicity test (OPPTS Test Guideline 870.4300); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) would help characterize the human health and environmental effects of the PMN substances. The Order does not require submission of the testing at any specified time or production volume. However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citations: 40 CFR 721.10612 (P-11-237); 721.10613 (P-11-328); 721.10614 (P-11-329); 721.10615 (P-11-330); 721.10616 (P-11-331); and 721.10617 (P-11-332).

PMN Number P-11-607

Chemical name: Polyaromatic Organophosphorus Compound (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: July 11, 2012.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an additive flame retardant (open, non-dispersive use). Based on test data on the PMN substance itself, EPA expects the PMN substance to hydrolyze under neutral and basic conditions. EPA does not expect significant human health concerns from the intact chemical, but there is uncertainty regarding the hydrolysis products. Based on test data on structurally similar phosphinate esters and submitted algae data on the PMN substance itself, EPA expects toxicity to aquatic organisms to occur at concentrations that exceed 6 ppb. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on findings that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to the environment, the substance may be produced in substantial quantities, may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance and its potential degradation products.

To protect against these risks the consent order requires:

- 1. Use of the substance only as described in the PMN.
- 2. Establishment and use of a hazard communication program.
- 3. No use of the substance that results in releases to surface water.

Recommended testing: EPA has determined that certain testing would help characterize the fate, environmental and human health effects of the PMN substance. The consent order contains two production limits. The PMN submitter has agreed not to exceed the first production volume limit without performing: A daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a washing machine study at basic pH based on the International Organization for Standardization (ISO) color fastness test to ascertain release rates with analytics to identify hydrolysis products (ISO 105); an inherent biodegradability test (OPPTS Test Guideline 835.3215); and a hydrolysis as a function of pH and temperature test (OPPTS Test Guideline 835.2130). If the results of the first tier of testing demonstrate that the PMN substance may cause adverse effects to humans or the environment, the PMN submitter has agreed to not exceed a production limit before conducting additional testing to ascertain whether those releases from representative enduse articles are in sufficient quantities to pose a significant risk.

EPA has also determined that a prenatal developmental toxicity study (OPPTS Test Guideline 870.3700 or OECD 414) using oral (gavage) in the rat would help characterize the human health effects of the PMN substance. The order does not require the submission of the prenatal developmental toxicity study at any specified time or production volume. However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10618.

PMN Number P-11-653

Chemical name: Perfluoroalkylethyl methacrylate copolymer (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: July 12, 2012.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (nonconfidential) use of the substance will be as a water and oil repellant. EPA has concerns for the formation of potential incineration or other decomposition products from the PMN substance. These perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, suggesting that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analog chemicals, including perfluorooctanoic acid (PFOA) and other perfluorinated carboxylates, such as the presumed environmental degradant of the PMN substance, perfluorohexanoic acid (PFHxA). There is pharmacokinetic and toxicological data in animals on PFOA, as well as epidemiological and blood monitoring data in humans. Toxicity studies on PFOA indicate developmental, reproductive, and systemic toxicity in various species, as well as cancer. These factors, taken together, raise concerns for potential adverse chronic effects from the presumed degradation product in humans and wildlife. The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that this substance may present an unreasonable risk of injury to human health and the environment, the substance may

be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance and its potential degradation products. To protect against these risks, the consent order requires risk notification. If the Company becomes aware that the PMN substance may present a risk of injury to human health or the environment, the Company must incorporate this new information, and any information on methods for protecting against such risk into a MSDS, within 90 days. The SNUR designates as a "significant new use" the absence of this protective measure.

Recommended testing: EPA has determined that the results of certain fate testing identified in the consent order would help characterize possible effects of the substance and its degradation products. The PMN submitter has agreed not to manufacture or import the PMN substance after September 30, 2014, without performing a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.5045 or OECD Test Guideline 302A); a UV/visible absorption test (OPPTS Test Guideline 830.7050); direct photolysis rate in water by sunlight test (OPPTS Test Guideline 835.2210); a hydrolysis as a function of pH and temperature test (OPPTS Test Guideline 835.2130 or OECD Test Guideline 111); an indirect photolysis screening test: sunlight photolysis in waters containing dissolved humic substances (OPPTS Test Guideline 835.5270); a photolysis on soils study using the phototransformation of chemicals on soil surfaces OECD Test Guideline 2005 Draft (located in the docket under docket ID number EPA-HQ-OPPT-2012-0740); aerobic and anaerobic transformation in aquatic sediment systems (OECD Test Guideline 308); and an anaerobic biodegradability of organic compounds in digested sludge by measurement of gas production test (OECD Test

Guideline 311). These tests are further detailed in the consent order. EPA has determined if the substance was to be sprayed by commercial or consumer applicants, that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a 60day holding period would help characterize possible effects of the substance and its degradation products. The consent order does not require submission of the inhalation testing at any specified time or production volume. However, the consent order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN will remain in effect until the consent order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10619.

PMN Number P-12-191

Chemical name: Oxirane, 2,2'-(phenylene)bis-.

CAS number: 30424-08-9.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a component of adhesives and composites. Based on structural activity relationship (SAR) of test data on analogous epoxides, EPA identified developmental and male reproductive toxicity and cancer concerns to workers exposed to the PMN substance via the inhalation route. In addition, based on EcoSAR analysis of test data on analogous epoxides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 10 ppb of the PMN substance in surface waters. As described in the PMN, significant inhalation exposures are not expected due to low vapor pressure when the substance is distributed with less than or equal to 5 percent impurities, and releases of the substance are not expected to result in surface water concentrations that exceed 10 ppb.

Therefore, EPA has not determined that the proposed manufacturing, processing, or use

of the substance may present an unreasonable risk. EPA has determined, however, that

any distribution of the substance with greater than 5 percent impurities, or any use of the

substance resulting in surface water concentrations exceeding 10 ppb may cause serious

health effects and significant adverse environmental effects. Based on this information,

the PMN substance meets the concern criteria at §721.170 (b)(1)(i)(C), (b)(3)(ii), and

(b)(4)(ii).

Recommended testing: EPA has determined that the results of a ready biodegradability

test (OPPTS Test Guideline 835.3110); a combined repeated-dose toxicity study with the

reproduction/developmental toxicity screening test (OECD Test Guideline 422) via the

inhalation route in rats; a carcinogenicity study (OECD Test Guideline 451); a fish early-

life stage toxicity test (OPPTS Test Guideline 850.1400); and a daphnid chronic toxicity

test (OPPTS Test Guideline 850.1300) would help characterize the human health and

environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10620.

PMN Number P-12-196

Chemical name: Distillation bottoms, alkylated benzene by-product (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non confidential) use of the substance

is for bromine recovery. Based on test data on the PMN substance and EcoSAR analysis

of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms

may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters.

As described in the PMN, releases of the substance are not expected to result in surface

water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at \$721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guidelines 850.4500) would help characterize the environmental effects of the PMN substance. EPA also recommends that the special considerations for conducting aquatic laboratory studies (OPPTS Test Guideline 850.1000) be followed to facilitate solubility in the test media, because of the PMN's low water solubility.

CFR citation: 40 CFR 721.10621.

PMN Number P-12-285

Chemical name: Copper(2+), tetraammine-, chloride (1:2).

CAS number: 10534-87-9.

Basis for action: The PMN states that the generic (non confidential) uses of the substance are as a raw material for production of copper chemicals and as a raw material for the production of animal feed micronutrients. Based on test data on the PMN substance and EcoSAR analysis of test data on analogous inorganic copper complexes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb

of the PMN substance in surface waters. As described in the PMN, releases of the

substance are not expected to result in surface water concentrations that exceed 3 ppb.

Therefore, EPA has not determined that the proposed manufacturing, processing, or use

of the substance may present an unreasonable risk. EPA has determined, however, that

any use of the substance resulting in surface water concentrations exceeding 3 ppb may

cause significant adverse environmental effects. Based on this information, the PMN

substance meets the concern criteria at §721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish BCF Test (OPPTS

Test Guideline 850.1730) would help characterize the environmental effects of the PMN

substance

CFR citation: 40 CFR 721.10622.

PMN Numbers P-12-298 and P-12-299

Chemical name: Vinylidene ester (generic).

CAS number: Not available.

Basis for action: The PMN states that the substance will be used as an adhesive. Based

on EcoSAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic

organisms may occur at concentrations that exceed 7 ppb of the PMN substance in

surface waters for greater than 20 days per year. This 20-day criterion is derived from

partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range

from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if

releases of the PMN substance to surface water exceed releases from the use described in

the PMN. For the use described in the PMN, environmental releases did not exceed 7 ppb

for more than 20 days per year. if releases of the PMN substances to surface water from

uses other than described in the PMN exceed the releases expected from the use described in the PMN. For the described use in the PMN, significant environmental releases are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that combined production volume of the two PMN substances exceeding 20,000 kilograms per year could result in exposures which may cause significant adverse environmental effects. Based on this information, the PMN substances meets the concern criteria at §721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guidelines 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guidelines 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances.

CFR citation: 40 CFR 721.10623.

PMN Number P-12-326

Chemical name: Dicyclohexylmethane-4,4'-diisocyanate, polymer with ethoxylated, propoxylated polyethers (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as part of 2-component reactive polyurethane adhesive resin. Based on analogous diisocyanate substances, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure to the PMN substance. Specifically, the Agency expects potential

toxicity to workers from dermal or inhalation exposure to the PMN substance when the molecular weight is less than 1000 daltons. For the uses described in the PMN and due to the use of personal protective equipment, significant worker exposure to the PMN substance where the molecular weight is less than 1000 daltons is unlikely, as dermal and inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that the manufacture, processing, or use of the substance where the molecular weight is less than 1000 daltons may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at §721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) and a skin sensitization test (OPPTS Test Guideline 870.2600) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10624.

PMN Numbers P-12-332 and P-12-333

Chemical name: Distillation bottoms, alkylated benzene by-product, brominated and bromo diphenyl alkane.

CAS number: Not available.

Basis for action: The PMNs state that the PMN substances will be used as a feed for a bromine recovery unit. Based on test data on analogous chemical substances, the Agency identified concerns for liver toxicity and the potential for other human health risks due to the possible formation of dioxins and furans. These concerns are for workers exposed to

the PMN substances by the inhalation and dermal routes. For the uses described in the PMNs and due to the use of personal protective equipment, significant worker exposure is unlikely, as dermal and inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that use of the substances other than as described in the PMNs may cause serious health effects. Based on this information, the PMN substances meet the concern criteria at §721.170(b)(3)(ii). Recommended testing: EPA has determined that the results of a 90-day oral toxicity in rodents test (OPPTS Test Guideline 870.3100) and either a determination of polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans from stationary sources study (EPA Method 23); or a polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) by high resolution gas chromatography / high resolution mass spectrometry (HRGC/HRMS) study (EPA Method 8290A); or a samesample determination of ultratrace levels of polybromodiphenylethers, polybromodibenzo-p-dioxins/furans, and polychlorodibenzo-p-dioxins/furans from combustion flue gas study (Wyrzykowska, B., Tabor, D., and Gullett, B. Anal. Chem., 2009, 81 (11), 4334–4342.) on each of the PMN substances would help characterize the human health effects of the PMN substances.

CFR citation: 40 CFR 721.10625.

PMN Number P-12-373

Chemical name: 1,4-Butanediol, polymer with substituted alkane and substituted methylene biscarbomonocycle, 2-hydroxyalkyl acrylate-blocked (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an abrasion resistant, formable dual-cure lacquer for screen printing. Based on test data on analogous acrylates and isocyanates, EPA identified concerns for respiratory and dermal sensitization and irritation to workers from exposure to the PMN substance. Additionally, the Agency identified low to moderate concern for mutagenicity, oncogenicity, and developmental toxicity for the low molecular weight acrylates. For the uses described in the PMNs significant worker exposure is unlikely because there are no applications generating a vapor, mist or aerosol, and there are no consumer exposures. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of these substances may present an unreasonable risk. EPA has determined, however, that any use of the substance in consumer products; or any use of the substance involving an application method that generates a vapor, mist, or aerosol may cause serious health effects. For the uses described in the PMN and due to the use of personal protective equipment, significant worker exposure is unlikely, as dermal and inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance in consumer products or in spray applications may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at §721.170 (b)(3)(ii).

Recommended testing: EPA has determined that a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) and a skin sensitization test (OPPTS Test Guideline 870.2600) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10626.

PMN Number P-12-430

Chemical name: Yttrium borate phosphate vanadate with europium and additional

dopants (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN

substance will be as a coating for the interior surface of glass lamps. Based on test data

on analogous chemical substances, EPA identified health concerns for lung effects if the

poorly soluble, respirable particles are inhaled. Additionally, due to the crystalline

structure of the PMN substance, the Agency identified concern for oncogenicity if the

PMN substance was inhaled. These concerns are for workers exposed to the PMN

substance by inhalation. For the use described in the PMN and at the production volume

stated in the PMN, significant worker inhalation exposure is not expected. Therefore,

EPA has not determined that the proposed manufacturing, processing, or use of the

substance may present an unreasonable risk. EPA has determined, however, that use of

the PMN substance other than as described in the PMN or use exceeding the annual

manufacture or import volume stated in the PMN may result in serious health effects.

Based on this information, the PMN substance meets the concern criteria at §721.170

(b)(1)(i)(c) and (b)(3)(ii).

Recommended testing: EPA has determined that a 90-day inhalation toxicity test

(OPPTS Test Guideline 870.3465) would help characterize the health effects of the PMN

substance.

CFR citation: 40 CFR 721.10627.

PMN Number P-12-432

Chemical name: Mixed metal oxalate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the PMN

substance will be as an intermediate precipitate used to produce phosphors. Based on test

data on analogous chemical substances, EPA identified health concerns for lung effects if

the poorly soluble, respirable particles are inhaled. Additionally, due to the crystalline

structure of the PMN substance, the Agency identified concern for oncogenicity if the

PMN substance was inhaled. These concerns are for workers exposed to the PMN

substance by inhalation. For the use described in the PMN and at the production volume

stated in the PMN, significant worker inhalation exposure is not expected. Therefore,

EPA has not determined that the proposed manufacturing, processing, or use of the

substance may present an unreasonable risk. EPA has determined, however, that use of

the PMN substance other than as described in the PMN or use exceeding the annual

manufacture or import volume stated in the PMN may result in serious health effects.

Based on this information, the PMN substance meets the concern criteria at §721.170

(b)(1)(i)(c) and (b)(3)(ii).

Recommended testing: EPA has determined that a 90-day inhalation toxicity test

(OPPTS Test Guideline 870.3465) would help characterize the health effects of the PMN

substance.

CFR citation: 40 CFR 721.10628.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for 8 of the 20 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to §721.160 (see Unit II.).

In the other 12 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at \$721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.

- EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory).

Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in §721.160(c)(3) and §721.170(d)(4). In accordance with §721.160(c)(3)(ii) and §721.170(d)(4)(i)(B), the effective date of this rule is [insert date 60 days after date of publication in the Federal Register] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before [insert date 30 days after date of publication in the Federal Register].

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [insert date 30 days after date of publication in the Federal Register], EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed

SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies.

EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of Rule to Uses Occurring Before Effective Date of the Rule

Significant new use designations for a chemical substance are legally established as of the date of publication of this direct final rule, [insert date of publication in the Federal Register].

To establish a significant "new" use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 8 chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no other person may commence such activities without first submitting a PMN. For chemical substances for which an NOC has not been submitted at this time, EPA concludes that the uses are not ongoing. However, EPA recognizes that prior to the effective date of the rule, when chemical substances identified in this SNUR are added to the TSCA Inventory, other persons may engage in a significant new use as defined in this rule before the effective date of the rule. However, 11 of the 20 chemical substances contained in this rule have CBI chemical identities, and

since EPA has received a limited number of post-PMN *bona fide* submissions (per §§720.25 and 721.11), the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

As discussed in the April 24, 1990 SNUR, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this direct final rule rather than as of the effective date of the rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notification requirements because a person could defeat the SNUR by initiating the significant new use before the rule became effective, and then argue that the use was ongoing before the effective date of the rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires.

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person meets the conditions of advance compliance under \$721.45(h), the person is considered exempt from the requirements of the SNUR.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).

2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see §720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP and OPPTS test guidelines referenced in this document electronically, please go to http://www.epa.gov/ocspp and select "Test Methods and Guidelines" or for guidelines not currently available on the Web site, EPA has placed a copy of that guideline in the public docket. The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at http://www.oecdbookshop.org or SourceOECD at http://www.sourceoecd.org. To access EPA Method 23 and Method 8290A, please go to http://www.epa.gov/ttn/emc/methods/method23.html and http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/8290a.pdf. To access the International Organization for Standardization (ISO) standard, ISO 105, please go to

http://www.ihs.com/products/industry-standards/org/iso/list/page9.aspx.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
 - Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1).

Under these procedures a manufacturer, importer, or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer, importer, or processor must show that it has a *bona fide* intent to manufacture, import, or process the chemical substance and must identify the specific use for which it intends to manufacture, import, or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture, import, or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers, importers, and processors can combine the *bona fide* submission under the procedure in §721.1725(b)(1) with that under §721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture, import, or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

According to §721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in §720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §8721.25 and 720.40. E-PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2012-0740.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This rule establishes SNURs for several new chemical substances that were the subject of PMNs and, in some cases, TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RAF)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

- 1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- 2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012, certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, so NTTAA section 12(d) (15 U.S.C. 272 note) does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

XIV. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

42

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 22, 2012.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9--[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In §9.1, add the following sections in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

| 40 CFR cita | ation | | | OMB control No. | | | |
|---|-------|---|-----------|-----------------|--|--|--|
| * | * | * | * | * | | | |
| Significant New Uses of Chemical Substances | | | | | | | |
| * | * | * | * | * | | | |
| 721.10611 | | | 2070-0012 | 2 | | | |
| 721.10612 | | | 2070-0012 | 2 | | | |
| 721.10613 | | | 2070-0012 | 2 | | | |
| 721.10614 | | | 2070-0012 | 2 | | | |
| 721.10615 | | | 2070-0012 | 2 | | | |
| 721.10616 | | | 2070-0012 | 2 | | | |

| 721.10617 | | | 2070-0012 | |
|-----------|---|---|-----------|---|
| 721.10618 | | | 2070-0012 | |
| 721.10619 | | | 2070-0012 | |
| 721.10620 | | | 2070-0012 | |
| 721.10621 | | | 2070-0012 | |
| 721.10622 | | | 2070-0012 | |
| 721.10623 | | | 2070-0012 | |
| 721.10624 | | | 2070-0012 | |
| 721.10625 | | | 2070-0012 | |
| 721.10626 | | | 2070-0012 | |
| 721.10627 | | | 2070-0012 | |
| 721.10628 | | | 2070-0012 | |
| * | * | * | * | * |

* * * * *

PART 721--[AMENDED]

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

4. Add §721.10611 to subpart E to read as follows:

§721.10611 Benzoic acid, 4-[(1-oxodecyl)oxy]-.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as benzoic acid, 4-[(1-oxodecyl)oxy]- (PMN P-11-135, CAS No. 86960-46-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) Industrial, commercial and consumer activities. Requirements as specified in §721.80(f) and (j)
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of \$721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 5. Add §721.10612 to subpart E to read as follows:

§721.10612 Distillates (lignocellulosic), C5-40.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as distillates (lignocellulosic), C5-40 (PMN P-11-327, CAS No. 1267611-99-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Protection in the workplace. Requirements as specified in §721.63(a)(1),
 (a)(3), (a)(4), (a)(6), (b)(concentration set at 0.1 percent), and (c). The following
 NIOSH-approved respirators with an APF of 10,000 meet the minimum requirements for §721.63(a)(4): Any NIOSH-certified pressure-demand or other positive pressure mode

(e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

- (A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.32 milligram/cubic meter (mg/m³) as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.
 - (B) [Reserved]
- (ii) *Hazard communication program*. Requirements as specified in §721.72(a), (b), (c), (d), (e)(concentration set at 0.1 percent), (f), and (g).
- (iii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (Where N=5, and 5 is an aggregate of releases for the following substances: distillates (lignocellulosic), C5-40 (PMN P-11-327, CAS No. 1267611-99-3); paraffin waxes (lignocellulosic) hydrotreated, C5-40 branched, cyclic and linear (PMN P-11-328, CAS No. 1267611-06-2); naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (PMN P-11-329, CAS No. 1267611-35-7); kerosene (lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear (PMN P-11-330, CAS No. 1267611-14-2); distillates (lignocellulosic), hydrotreated, C8-26 branched, cyclic, and linear (PMN P-11-331, CAS No. 1267611-11-9); and residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear (PMN P-11-332, CAS No. 1267611-71-1)).

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a) through (h) and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.
 - 6. Add §721.10613 to subpart E to read as follows:

§721.10613 Paraffin waxes (lignocellulosic) hydrotreated, C5-40 - branched, cyclic and linear.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as paraffin waxes (lignocellulosic) hydrotreated, C5-40 branched, cyclic and linear (PMN P-11-328, CAS No. 1267611-06-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in §721.63 (a)(1), (a)(3), (a)(4), (a)(6), (b) (concentration set at 0.1 percent), and (c). The following NIOSH-approved respirators with an APF of 10,000 meet the minimum requirements for §721.63(a)(4): Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.
- (A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure

limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.32 milligram/cubic meter (mg/m³) as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

(B) [Reserved]

- (ii) Hazard communication program. Requirements as specified in §721.72(a),(b), (c), (d), (e)(concentration set at 0.1 percent), (f), and (g).
- (iii) *Release to water*. Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) (Where N=5, and 5 is an aggregate of releases for the following substances: distillates (lignocellulosic), C5-40 (PMN P-11-327, CAS No. 1267611-99-3); paraffin waxes (lignocellulosic) hydrotreated, C5-40 branched, cyclic and linear (PMN P-11-328, CAS No. 1267611-06-2); naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (PMN P-11-329, CAS No. 1267611-35-7); kerosene (lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear (PMN P-11-330, CAS No. 1267611-14-2); distillates (lignocellulosic), hydrotreated, C8-26 branched, cyclic, and linear (PMN P-11-331, CAS No. 1267611-11-9); and residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear (PMN P-11-332, CAS No. 1267611-71-1)).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a) through (h) and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
 - 7. Add §721.10614 to subpart E to read as follows:

§721.10614 Naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (PMN P-11-329, CAS No. 1267611-35-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in §721.63(a)(1), (a)(3), (a)(4), (a)(6), (b) (concentration set at 0.1 percent), and (c). The following NIOSH-approved respirators with an APF of 10,000 meet the minimum requirements for §721.63(a)(4): Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.
- (A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.32 milligram/cubic meter (mg/m³) as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the §721.63 respirator

requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

- (B) [Reserved]
- (ii) Hazard communication program. Requirements as specified in §721.72(a),(b), (c), (d), (e)(concentration set at 0.1 percent), (f), and (g).
- (iii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (Where N=5, and 5 is an aggregate of releases for the following substances: distillates (lignocellulosic), C5-40 (PMN P-11-327, CAS No. 1267611-99-3); paraffin waxes (lignocellulosic) hydrotreated, C5-40 branched, cyclic and linear (PMN P-11-328, CAS No. 1267611-06-2); naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (PMN P-11-329, CAS No. 1267611-35-7); kerosene (lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear (PMN P-11-330, CAS No. 1267611-14-2); distillates (lignocellulosic), hydrotreated, C8-26 branched, cyclic, and linear (PMN P-11-331, CAS No. 1267611-11-9); and residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear (PMN P-11-332, CAS No. 1267611-71-1)).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a) through (h) and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.

8. Add §721.10615 to subpart E to read as follows:

§721.10615 Kerosene (lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as kerosene (lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear (PMN P-11-330, CAS No. 1267611-14-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in §721.63(a)(1), (a)(3), (a)(4), (a)(6), (b) (concentration set at 0.1 percent), and (c). The following NIOSH-approved respirators with an APF of 10,000 meet the minimum requirements for §721.63(a)(4): Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.
- (A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.32 milligram/cubic meter (mg/m³) as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

(B) [Reserved]

- (ii) Hazard communication program. Requirements as specified in §721.72(a),(b), (c), (d), (e)(concentration set at 0.1 percent), (f), and (g).
- (iii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (Where N=5, and 5 is an aggregate of releases for the following substances: distillates (lignocellulosic), C5-40 (PMN P-11-327, CAS No. 1267611-99-3); paraffin waxes (lignocellulosic) hydrotreated, C5-40 branched, cyclic and linear (PMN P-11-328, CAS No. 1267611-06-2); naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (PMN P-11-329, CAS No. 1267611-35-7); kerosene (lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear (PMN P-11-330, CAS No. 1267611-14-2); distillates (lignocellulosic), hydrotreated, C8-26 branched, cyclic, and linear (PMN P-11-331, CAS No. 1267611-11-9); and residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear (PMN P-11-332, CAS No. 1267611-71-1)).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a) through (h) and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
 - 9. Add §721.10616 to subpart E to read as follows:

§721.10616 Distillates (lignocellulosic), hydrotreated, C8-26 - branched, cyclic, and linear.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as distillates (lignocellulosic), hydrotreated, C8-26 -

branched, cyclic, and linear (PMN P-11-331, CAS No. 1267611-11-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in §721.63(a)(1), (a)(3), (a)(4), (a)(6), (b) (concentration set at 0.1 percent), and (c). The following NIOSH-approved respirators with an APF of 10,000 meet the minimum requirements for §721.63(a)(4): Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.
- (A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.32 milligram/cubic meter (mg/m³) as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.
 - (B) [Reserved]
- (ii) Hazard communication program. Requirements as specified in §721.72(a),(b), (c), (d), (e)(concentration set at 0.1 percent), (f), and (g).
- (iii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (Where N=5, and 5 is an aggregate of releases for the following substances:

distillates (lignocellulosic), C5-40 (PMN P-11-327, CAS No. 1267611-99-3); paraffin waxes (lignocellulosic) hydrotreated, C5-40 - branched, cyclic and linear (PMN P-11-328, CAS No. 1267611-06-2); naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (PMN P-11-329, CAS No. 1267611-35-7); kerosene (lignocellulosic), hydrotreated, C8-16-branched, cyclic and linear (PMN P-11-330, CAS No. 1267611-14-2); distillates (lignocellulosic), hydrotreated, C8-26 - branched, cyclic, and linear (PMN P-11-331, CAS No. 1267611-11-9); and residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear (PMN P-11-332, CAS No. 1267611-71-1)).

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a) through (h) and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.
 - 10. Add §721.10617 to subpart E to read as follows:

§721.10617 Residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as residual oils (lignocellulosic), hydrotreated, C20-40-branched, cyclic, and linear (PMN P-11-332, CAS No. 1267611-71-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Protection in the workplace*. Requirements as specified in §721.63(a)(1), (a)(3), (a)(4), (a)(6), (b) (concentration set at 0.1 percent), and (c). The following NIOSH-approved respirators with an APF of 10,000 meet the minimum requirements for §721.63(a)(4): Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.
- (A) As an alternative to the respiratory requirements listed in paragraph (a)(2)(i), a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.32 milligram/cubic meter (mg/m³) as an 8-hour time-weighted average. Persons who wish to pursue NCELs as an alternative to the §721.63 respirator requirements may request to do so under §721.30. Persons whose §721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.
 - (B) [Reserved]
- (ii) Hazard communication program. Requirements as specified in §721.72(a),(b), (c), (d), (e)(concentration set at 0.1 percent), (f), and (g).
- (iii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) (Where N=5, and 5 is an aggregate of releases for the following substances: distillates (lignocellulosic), C5-40 (PMN P-11-327, CAS No. 1267611-99-3); paraffin waxes (lignocellulosic) hydrotreated, C5-40 branched, cyclic and linear (PMN P-11-328, CAS No. 1267611-06-2); naphtha (lignocellulosic), hydrotreated, C5-12-branched, cyclic and linear (PMN P-11-329, CAS No. 1267611-35-7); kerosene (lignocellulosic),

hydrotreated, C8-16-branched, cyclic and linear (PMN P-11-330, CAS No. 1267611-14-2); distillates (lignocellulosic), hydrotreated, C8-26 - branched, cyclic, and linear (PMN P-11-331, CAS No. 1267611-11-9); and residual oils (lignocellulosic), hydrotreated, C20-40- branched, cyclic, and linear (PMN P-11-332, CAS No. 1267611-71-1)).

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a) through (h) and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.
 - 11. Add §721.10618 to subpart E to read as follows:

§721.10618 Polyaromatic organophosphorus compound (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as polyaromatic organophosphorus compound (PMN P-11-607) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been embedded in a solid polymer matrix.
 - (2) The significant new uses are:
- (i) Hazard communication program. Requirements as specified in §721.72(a),(b), (c). (d), (e), (f), (g)(3)(i), (g)(3)(ii), and (g)(4)(iii).
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(j) and (q).

- (iii) *Release to water*. Requirements as specified in §721.90(a)(1), (b)(1), and (c)(1).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a), (b), (c), (f), (g), (h), (i) and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of \$721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
 - 12. Add §721.10619 to subpart E to read as follows:

§721.10619 Perfluoroalkylethyl methacrylate copolymer (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as perfluoroalkylethyl methacrylate copolymer (PMN P-11-653) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Hazard communication program*. A significant new use of this substance is any manner or method of manufacture, import, or processing associated with any use of this substance without providing risk notification as follows:
- (A) If as a result of the test data required under the TSCA section 5(e) consent order for this substance, the employer becomes aware that this substance may present a

risk of injury to human health or the environment, the employer must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet (MSDS) as described in §721.72(c) within 90 days from the time the employer becomes aware of the new information. If this substance is not being manufactured, imported, processed, or used in the employer's workplace, the employer must add the new information to a MSDS before the substance is reintroduced into the workplace.

- (B) The employer must ensure that persons who will receive the PMN substance from the employer, or who have received the PMN substance from the employer within 5 years from the date the employer becomes aware of the new information described in paragraph (a)(2)(i)(A) of this section, are provided an MSDS containing the information required under paragraph (a)(2)(i)(A) within 90 days from the time the employer becomes aware of the new information.
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(p)(any amount after September 30, 2014).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125 (a), (b), (c), (f), (h), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
 - 13. Add §721.10620 to subpart E to read as follows:

§721.10620 Oxirane, 2,2'-(phenylene)bis-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as oxirane, 2,2'-(phenylene)bis- (PMN P-12-191, CAS No. 30424-08-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(j)(distribution of chemical substance with less than or equal to 5 percent impurities).
- (ii) Release to water. Requirements as specified in $\S721.90(a)(4)$, (b)(4), and (c)(4) (N= 10).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a), (b), (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance,
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this significant new use rule.
 - 14. Add §721.10621 to subpart E to read as follows:

§721.10621 Distillation bottoms, alkylated benzene by-product (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as distillation bottoms, alkylated benzene by-

product (PMN P-12-196) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) Release to Water. Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) (N= 1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
 - 15. Add §721.10622 to subpart E to read as follows:

§721.10622 Copper(2+), tetraammine-, chloride (1:2).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as copper(2+), tetraammine-, chloride (1:2) (PMN P-12-285, CAS No. 10534-87-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Release to Water. Requirements as specified in §721.90(a)(4), (b)(4), and (c)(4) (N=3).
 - (ii) [Reserved]

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
 - 16. Add §721.10623 to subpart E to read as follows:

§721.10623 Vinylidene ester (generic).

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substances identified generically as vinylidene ester (PMNs P-12-298 and P-12-299) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(s)(20,000 kilograms of the aggregate of the two chemical substances).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a), (b),(c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
 - 17. Add §721.10624 to subpart E to read as follows:

§721.10624 Dicyclohexylmethane-4,4'-diisocyanate, polymer with ethoxylated, propoxylated polyethers (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as dicyclohexylmethane-4,4'-diisocyanate, polymer with ethoxylated, propoxylated polyethers (PMN P-12-326) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(j) (manufacture, processing, or use where the molecular weight is 1000 daltons or more).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
 - 18. Add §721.10625 to subpart E to read as follows:

§721.10625 Distillation bottoms, alkylated benzene by-product, brominated and bromo diphenyl alkane (generic).

(a) Chemical substances and significant new uses subject to reporting. (1) The chemical substances identified generically as distillation bottoms, alkylated benzene by-product, brominated and bromo diphenyl alkane (PMNs P-12-332 and P-12-333) are

subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(j)(feed for a bromine recovery unit).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 19. Add §721.10626 to subpart E to read as follows:

§721.10626 1,4-Butanediol, polymer with substituted alkane and substituted methylene biscarbomonocycle, 2-hydroxyalkyl acrylate-blocked (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as 1,4-butanediol, polymer with substituted alkane and substituted methylene biscarbomonocycle, 2-hydroxyalkyl acrylate-blocked (PMN P-12-373) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(o) and (y)(1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in §721.125(a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.
 - 20. Add §721.10627 to subpart E to read as follows:

§721.10627 Yttrium borate phosphate vanadate with europium and additional dopants (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as yttrium borate phosphate vanadate with europium and additional dopants (PMN P-12-430) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in §721.80(j) and (s).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a), (b),(c), and (i) are applicable to manufacturers, importers, and processors of this substance.

- (2) *Limitations or revocation of certain notification requirements*. The provisions of §721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 21. Add §721.10628 to subpart E to read as follows:

§721.10628 Mixed metal oxalate (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as mixed metal oxalate (PMN P-12-432) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Industrial, commercial, and consumer activities. Requirements as specified in §721.80(j) and (s).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in §721.125(a), (b),(c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of §721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of §721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

[FR Doc. 2012-26658 Filed 11/01/2012 at 8:45 am; Publication Date: 11/02/2012]